

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 06 June 2000 (06.06.00)	
International application No. PCT/DK99/00501	Applicant's or agent's file reference 98023-WO
International filing date (day/month/year) 23 September 1999 (23.09.99)	Priority date (day/month/year) 23 September 1998 (23.09.98)
Applicant HANSEN, Henrik, Christian et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

10 April 2000 (10.04.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Nestor Santesso
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT/DK99/00501
PATENTAFDELINGEN

- 1 NOV. 1999
6017-02

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

NILAUSEN, Kim
Coloplast A/S
Patent Dept.
Holtedam 1
DK-3050 Humlebaek
DANEMARK

Date of mailing (day/month/year) 27 October 1999 (27.10.99)	
Applicant's or agent's file reference 98023-WO	IMPORTANT NOTIFICATION
International application No. PCT/DK99/00501	International filing date (day/month/year) 23 September 1999 (23.09.99)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 23 September 1998 (23.09.98)
Applicant COLOPLAST A/S et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
23 Sept 1998 (23.09.98)	PA 1998 01196	DK	13 Octo 1999 (13.10.99)

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. (41-22) 740.14.35</p>	<p>Authorized officer Taïeb Akremi TA</p> <p>Telephone No. (41-22) 338.83.38</p>
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PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) 98023-WO

Box No. I TITLE OF INVENTION

Catheter set

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark

☐ This person is also inventor.

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+45 49 11 11 11

Facsimile No.

+45 49 11 15 55

Teleprinter No.

41.175 cinter

State (that is, country) of nationality:
DK

State (that is, country) of residence:
DK

This person is applicant
for the purposes of:

☐ all designated
States

☒ all designated States except
the United States of America

☐ the United States
of America only

☐ the States indicated in
the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

HANSEN, Henrik Christian.
Smedebakken 24
DK-2990 Nivaa
Denmark

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box
is marked, do not fill in below.)

State (that is, country) of nationality:
DK

State (that is, country) of residence:
DK

This person is applicant
for the purposes of:

☐ all designated
States

☐ all designated States except
the United States of America

☒ the United States
of America only

☐ the States indicated in
the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☐ agent

☒ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark
Att.: Mr. Kim Nilausen, Patent Department

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Facsimile No.

+45 49 11 18 49

Teleprinter No.

41.175 cinter

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

TANGHOEJ, Allan
Jellerød Have 59
DK-2980 Kokkedal
Denmark

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:
DK

State (that is, country) of residence:
DK

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

HORSBOEL, Niels
Torvet 4D, st.
DK-3400 Hillerød
Denmark

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:
DK

State (that is, country) of residence:
DK

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V. DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- ☒ **AP** ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA** Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> AE United Arab Emirates | <input checked="" type="checkbox"/> LR Liberia |
| <input checked="" type="checkbox"/> AL Albania | <input checked="" type="checkbox"/> LS Lesotho |
| <input checked="" type="checkbox"/> AM Armenia | <input checked="" type="checkbox"/> LT Lithuania |
| <input checked="" type="checkbox"/> AT Austria and Utility Model | <input checked="" type="checkbox"/> LU Luxembourg |
| <input checked="" type="checkbox"/> AU Australia | <input checked="" type="checkbox"/> LV Latvia |
| <input checked="" type="checkbox"/> AZ Azerbaijan | <input checked="" type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input checked="" type="checkbox"/> BG Bulgaria | |
| <input checked="" type="checkbox"/> BR Brazil | <input checked="" type="checkbox"/> MN Mongolia |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> MW Malawi |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CZ Czech Republic and Utility Model | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> DE Germany and Utility Model | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> DK Denmark and Utility Model | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> EE Estonia and Utility Model | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> FI Finland and Utility Model | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> GB United Kingdom | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> GD Grenada | <input checked="" type="checkbox"/> SK Slovakia and Utility Model |
| <input checked="" type="checkbox"/> GE Georgia | <input checked="" type="checkbox"/> SL Sierra Leone |
| <input checked="" type="checkbox"/> GH Ghana | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GM Gambia | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> TR Turkey |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> ID Indonesia | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> IN India | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> IS Iceland | |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> YU Yugoslavia |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> ZA South Africa |
| | <input checked="" type="checkbox"/> ZW Zimbabwe |

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

☐
☐

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)


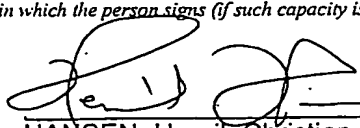
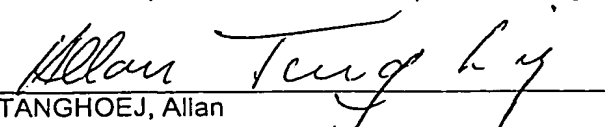

Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application:* regional Office	international application: receiving Office
item (1) (23.09.98) 23 September 1998	PA 1998 01196	DK		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1)

* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY									
Choice of International Searching Authority (ISA) (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used): ISA / SE	Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority): <table style="width: 100%;"> <tr> <td style="width: 33%;">Date (day/month/year)</td> <td style="width: 33%;">Number</td> <td style="width: 33%;">Country (or regional Office)</td> </tr> <tr> <td>4 November 1998</td> <td>DK98/00139</td> <td>DK</td> </tr> </table>			Date (day/month/year)	Number	Country (or regional Office)	4 November 1998	DK98/00139	DK
Date (day/month/year)	Number	Country (or regional Office)							
4 November 1998	DK98/00139	DK							

Box No. VIII CHECK LIST; LANGUAGE OF FILING	
This international application contains the following number of sheets: request : 4 description (excluding sequence listing part) : 10 claims : 2 abstract : 1 drawings : 4 sequence listing part of description : Total number of sheets : 21	This international application is accompanied by the item(s) marked below: 1. <input checked="" type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input checked="" type="checkbox"/> other (specify): Copy of ITS Report No. DK98/00139
Figure of the drawings which should accompany the abstract: Fig. 1	Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT	
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).	
Coloplast A/S  PEDERSEN, Jens Kristian Development Manager	 HANSEN, Henrik Christian
 TANGHOEJ, Allan	 HORSBOEL, Niels

For receiving Office use only	
1. Date of actual receipt of the purported international application: 3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application: 4. Date of timely receipt of the required corrections under PCT Article 11(2): 5. International Searching Authority (if two or more are competent): ISA /	2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received:
6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.	

For International Bureau use only
Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <i>J.</i>	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/DK99/00501	International filing date (<i>day/month/year</i>) 23/09/1999	Priority date (<i>day/month/year</i>) 23/09/1998
International Patent Classification (IPC) or national classification and IPC A61M25/01		
Applicant COLOPLAST A/S et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 10/04/2000	Date of completion of this report 07.12.2000
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Schießl, W Telephone No. +49 89 2399 7436 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK99/00501

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

Description, pages:

1-10 as originally filed

Claims, No.:

7-9 as originally filed

1-6 with telefax of 24/11/2000

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK99/00501

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-4, 6, 9
	No:	Claims	1, 5, 7, 8
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-9
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Section V

- 1 Reference is made to the following documents (D) cited in the International Search Report:

D1: WO 97 / 26937 (ISRAELSSON ANETTE ET AL) 31 July 1997

D2: WO 98 / 11932 (KAYEROD HELLE ET AL) 26 March 1998

D3: GB-A-2 284 764 (MCLEOD PATRICK) 21 June 1995

D4: US-A-5 147 341 (STARKE RICHARD ET AL) 15 September 1992

D5: US-A-2 856 932 (GRIFFITTS JAMES) 21 October 1958

- 2 Novelty (Article 33(2) PCT)

- 2.1 The present International Application does not meet the requirements of Article 33(2) PCT because the subject-matter of claim 1 is not new:

Document D5 discloses a catheter set (col. 3, ll. 16 to col. 4, l. 47, figs. 1-5) comprising a catheter (2) and a package (10), wherein an elongated part of the package (neck 12; cf. also VIII, 1 below) forms a tube (fig. 2) for accommodation of the catheter, the catheter comprising a proximal part (portion of body 14 that in use extends from neck 12, fig. 4), a sealing part (an intermediate portion of body 14 in use located at a proximal portion of neck 12) for providing a seal between the catheter and the elongated part of the package during use (col. 3, ll. 35-37) and a flexible tubular distal part (remaining distal portion of body 14 and rearward end 8; col. 1, ll. 33-35; cf. VIII, 2) separated by the sealing part from the proximal part (fig. 4), the flexible distal part having an inner diameter at least as large as the inner diameter of the proximal part (col. 2, l. 38) and being long enough to occupy said elongated part of the package (fig. 4), and, therefore, all features of claim 1.

- 2.2 D3 and D4 also make known a catheter set according to claim 1 (D3: abstract, claim 1, fig. 2/3, part 5 extending into the package; D4: col. 3, ll. 5-7, fig. 10, part 22 extending into a narrow part of the package; cf. VIII, 2 below).

- 2.3 Dependent claims 5, 7, 8, do not contain any features which, in combination with

the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, since and D5 disclose further:

- a tubular distal part being made from an extrudable, moldable material as recited in claim 5 (col. 3, l. 16), and
- a package having an elongated narrow part and being provided with a sealing device on the exterior side of the package according to claims 7 and 8 (fig. 4, part 12, cf. VIII, 1; fig. 8).

3 Inventive step (Article 33(3) PCT)

The remaining dependent claims do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, since D1 discloses

- a set comprising a catheter with a hydrophilic coating (p. 10, l. 4) and wetting fluid integrated into the package as defined in claims 2 and 3 (p. 10, ll. 15-19),

and in that

- a tubular distal part having an inner diameter larger than that of the proximal part (claim 4) and being transversely corrugated (claim 6),
- a sealing device comprising an adhesive sheet (claim 9),

are slight constructional changes which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen (cf. p. 6, ll. 1, 2, of present application and D5, col. 1, ll. 48-52, fig. 8).

Section VII

All features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Section VIII

The present international application does not meet the requirements of Article 6 PCT.

- 1 The "elongated part of the package" as defined in claim 1 includes elongated

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/DK99/00501

tubular portions of any length at the proximal end of the package including the seal between the catheter and said elongated part. Moreover, there appears to be some confusion in the application about the terms used for said part and, consequently, the length of the flexible tubular distal portion / section (cf. claims 1, 7, and page 7, ll. 20-24, p. 8, ll. 20-26).

- 2 The term "flexible tubular section" used in claim 1 is interpreted to extend in one respect at least to conical plastic syringe connectors at the distal end of catheters, since any solid (plastic) material is flexible to some extent. In view of the description (p. 8, ll. 18-29), it appears that on the other hand said tubular section should be at least **stiffer** than the package to improve the protection against kinking or squeezing thereof.
- 3 The function of the sealing device specified in claim 8 should have been clarified (cf. p. 6, ll. 18, 19, of the description) to avoid confusion with the sealing part as defined in claim 1.
- 4 The statements in the description "inventive shape of the catheter .." (pp. 2, 4) and "sealing system according to the invention .." (p. 3), the omission of the sealing function of the sealing part in the embodiment on page 3, ll. 14-22 do not correspond to the scope of claim 1. This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear.

CLAIMS

1. A catheter set comprising a catheter and a package for storing of the catheter before use and for collecting or discharging urine wherein an elongated part of the package forms a tube for accommodation of the catheter, the catheter
5 comprises a proximal part to be inserted into the urethra and a sealing part for providing a seal between the catheter and the elongated part of the package during use, CHARACTERISED IN that the catheter further comprises a distal part in the form of a flexible tubular section (4) having an inner diameter at least as large as the inner diameter of the proximal part of the catheter wherein the
10 sealing part is separating the proximal part of the catheter and the tubular distal part, and wherein the length of the flexible tubular distal part (4) is at least long enough to occupy the elongated part of the package.
2. A catheter set according to claim 1, CHARACTERISED IN that the proximal part of the catheter has a hydrophilic coating.
- 15 3. A catheter set according to claim 1 or 2, CHARACTERISED IN that the set comprises a wetting fluid integrated into the package.
4. A catheter set according to any of claims 1 - 3, CHARACTERISED IN that the tubular distal part of the catheter has an inner diameter larger than the inner diameter of the proximal part of the catheter.
- 20 5. A catheter set according to any of claims 1 - 4, CHARACTERISED IN that the tubular part is made from an extrudable, mouldable material such as a polyolefin such as polyethylene (PE) or polypropylene (PP) or a copolymer of polyethylene such as ethylene vinyl acetate (EVA) or polyvinyl chloride (PVC) or polyvinylidene chloride.
- 25 6. A catheter set according any of claims 1 - 5, CHARACTERISED IN that the tubular distal part of the catheter is transversely corrugated.

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/DK99/00501</p> <p>(22) International Filing Date: 23 September 1999 (23.09.99)</p> <p>(30) Priority Data: PA 1998 01196 23 September 1998 (23.09.98) DK</p> <p>(71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Høltedam 1, DK-3050 Humlebaek (DK).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): HANSEN, Henrik, Christian [DK/DK]; Smedebakken 24, DK-2990 Nivaa (DK). TANGHOEJ, Allan [DK/DK]; Jellerød Have 59, DK-2980 Kokkedal (DK). HORSBOEL, Niels [DK/DK]; Torvet 4D, st., DK-3400 Hillerød (DK).</p> <p>(74) Common Representative: COLOPLAST A/S; Nilausen, Kim, Patent Dept., Høltedam 1, DK-3050 Humlebaek (DK).</p>		<p>(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p>	

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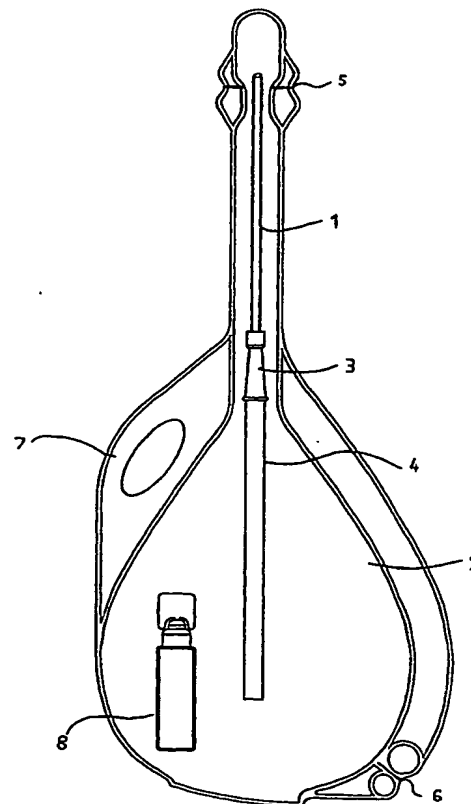
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Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: CATHETER SET

(57) Abstract

A catheter set comprising a catheter and a package for storing of the catheter before use and for collecting or discharging urine, wherein an elongated part of the package forms a tube and wherein the catheter has a proximal part to be inserted into the urethra, a distal part in the form of a tubular section having an inner diameter at least as large as the inner diameter of the part of the proximal part of the catheter and a sealing part separating the proximal part of the catheter and the tubular distal part. The inventive shape of the catheter combined with the shape of the package prevents a blocking of the free flow of urine from the urethra into the package.



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TITLE

Catheter set.

FIELD OF THE INVENTION

The present invention relates to a catheter set comprising a catheter and a
5 package for both storing of the catheter before use and for collecting or
discharging urine.

BACKGROUND OF THE INVENTION

Urinary catheter sets comprising a catheter having a hydrophilic coating, a
wetting receptacle and a wetting fluid are disclosed in WO publication No.
10 98/11932 (Coloplast A/S) and in WO publication no. 97/26937 (Astra Aktiebolag).

Both publications describe catheter sets comprising both a catheter and a
package, and in both publications an elongated part of the package forms a tube
and is used for leading urine either to the inside of the package for later disposal
or to an exterior container e.g. a toilet bowl for immediate disposal.

- 15 The use of such catheter sets is described by referring to figure 1 of WO
97/26937. First the proximal portion of the pocket 2 is torn off and the elongate
shaft 18 of the catheter 3 is manoeuvred through the opening in the proximal end
of the pocket 2 and into the urethra of the patient until a flared distal portion 16
forms a mechanical seal connection with the opening. Urine in the bladder of the
20 patient is transported through the lumen of the catheter 3 into the urine collection
chamber 12. After emptying the bladder the catheter 3 is manoeuvred back
inside the bag 1 and the open end of the pocket 2 closed off for example by tying
a knot with the material defining the pocket 2 or clamping the pocket with a
clamp.
- 25 A disadvantage with these catheter sets is that the mechanical seal connection
between the flared distal portion of the catheter and the proximal part of the
package does not always work properly and the result is that urine flows
backward and out of the package, especially due to restriction of the flow from

the catheter into the receptacle due to folding, twisting or kinking of the elongate part of the device leading from the catheter to the receptacle..

GB 2031735 discloses a catheter set comprising a catheter within a package for collecting urine. So does GB 2284764, GB 2033231 and US 5147341. The

- 5 rearward end of these catheters are either flared outwardly or provided with an arresting member to keep the catheter from leaving the package unintendedly. Non of these references provides an elongated part of the package to serve as a wetting receptacle for wetting the catheter.

US 2856932 discloses a catheter set comprising a catheter and a package

- 10 having an elongated part covering part of the catheter to assist insertion of the catheter in a non-contaminating manner. At the rearward end of the catheter it is flared outwardly to keep the catheter in place in relation to the package during use. This shape of entrance into the package provides the same disadvantages and risks of flow restriction as mentioned above due to possible occurrence of
- 15 twisting or kinking at the link between the elongated and the broader part of the package. Furthermore a considerable length of the catheter is "inactivated" by not being able to leave the elongated neck and such extra length would have to be added to the catheter in addition to the necessary "active length" causing considerable extra costs. For short catheters this extra length constitutes a
- 20 considerable part of the total length of the catheter.

The object of the invention is to solve this problem and provide a catheter set preventing the risk of spilling urine over cloth or surroundings when performing intermitting catheterisation, especially when performed by the patient him- /herself, and at the same time to provide a catheter set which is simple and inexpensive

25 to produce. It has surprisingly been found that the above drawbacks may be overcome using a catheter set according to the invention.

BRIEF DESCRIPTION OF THE INVENTION

The present invention relates to a catheter set comprising a catheter and a package for both storing of the catheter before use and for collecting or

- 30 discharging urine. The inventive shape of the catheter combined with the shape

of the package prevents blocking of the free flow of urine from the urethra into the package during use by securing the relatively soft and pliable package from kinking or squeezing.

BRIEF DESCRIPTION OF THE DRAWINGS

- 5 The invention will be explained more in detail with reference to the accompanying drawings showing embodiments of the invention and in

Fig. 1 shows an embodiment of a catheter set according to the invention,

Fig. 2 shows the embodiment of Fig. 1 ready for use,

Fig. 3 shows another embodiment of a catheter set according to the invention,

- 10 Fig. 4 shows a sealing system according to the invention in an enlarged scale, and

Fig. 5 shows the embodiment of Fig. 3 in a sealed state.

DETAILED DESCRIPTION OF THE INVENTION

- The present invention relates to a catheter set comprising a catheter and a
15 package for storing of the catheter before use and for collecting or discharging urine, wherein an elongated part of the package forms a tube for accommodating of the catheter. The catheter comprises a proximal part to be inserted into the urethra and a distal part in the form of a tubular section having an inner diameter at least as large as the inner diameter of the part of the proximal part of the
20 catheter, and a sealing part separating the proximal part of the catheter and the tubular distal part. The length of the tubular distal part is at least long enough to occupy the elongated part of the package.

- The sealing part may e.g. be a part of the catheter having an increased diameter. Such a sealing part will also function as a stop preventing the catheter from
25 falling out of the package and, at the same time function as a seal during use preventing spilling of urine during catheterisation.

The proximal part of the catheter will usually have an essentially uniform thickness of material as will the distal part.

It is very practical when the sealing part is separating the proximal part of the catheter and the tubular distal part as this provides safety against trying to insert the tubular part into the urethra and also ensures that the tubular part remains in the package for ensuring the free flow of urine into the package.

- 5 When in use, the distal tubular part of the catheter of the invention reaches into the upper part of the package and keeps the front and rear parts thereof apart and thus prevents a blocking of the free flow of urine from the urethra into the package. Thus the length of the tubular distal part of the catheter is at least as long as the length of the elongated part of the package. In the absence of the
- 10 tubular part, urine flowing through the catheter may meet an obstacle if for example the package is folded or squeezed and thus, the urine will fill up the upper part of the package and establish a back pressure on the sealing between the catheter and the package. When a tubular part of the catheter is inside the package as an extension of the catheter it thus prevents the flow of urine from
- 15 being disturbed in the upper part of the relatively soft package, and the flow of urine will be directed downwards until the package is full. The inner diameter of the tubular part of the catheter must be of at least of the same dimension as the proximal part of the in order not to hamper the free flow of urine from the bladder through the catheter and into the package. Thus the inventive shape of the
- 20 catheter in combination with the shape of the package prevents a blocking of the free flow of urine form urethra into the package.

The tubular part of the catheter may be a prolonged part of the catheter itself or a separate tubular piece which is connected to the catheter.

- In a preferred embodiment of the invention the proximal part of the catheter has
- 25 a hydrophilic coating. A hydrophilic coating may be any hydrophilic coating known per se for use for hydrophilic coated catheters and the coating may be applied using any method known per se for applying a hydrophilic coating to a catheter.

- The catheter set according to the invention preferably comprises a wetting fluid
- 30 integrated into the package in order to enable activation of a hydrophilic coating

irrespectively of the access to pure water. The wetting fluid may be sterilised water or saline.

The elongated shape of part of the package is especially useful when the catheter has a hydrophilic coating of the type needing activation by addition of wetting fluid. When the elongated part of the package accommodates the catheter - at least during the wetting process, but preferably already when package is produced and packed ready for sale - the amount of wetting fluid needed to ensure proper wetting is drastically reduced compared to the amount needed if wetting was to take place in the wider part of a package.

- 10 It is understood that the location of the catheter in the elongated part can take place already when the package is produced. But also the package can be produced with the catheter situated inside the broader part of the package in which situation the catheter is introduced into the elongated part of the package at any time prior to use to let the elongated part of the package accommodate the catheter.

In one embodiment of the invention the tubular distal part of the catheter has an inner diameter larger than the inner diameter of the proximal part of the catheter. Thus, no extra resistance against the flow will occur and, as the outer diameter thereof is consequently also greater, the transition between the two parts of the catheter may function as a stop and sealing.

The tubular part of a catheter is preferably made from an extrudable, mouldable material such as a polyolefin such as polyethylene (PE) or polypropylene (PP) or a copolymer of polyethylene such as ethylene vinyl acetate (EVA) or polyvinyl chloride (PVC) or polyvinylidene chloride or a polyurethane (PU) or a silicone. It is envisaged that the proximal and distal tubular part of the catheter and the sealing part may be produced as an integrated unit from the same material by a combination of injection moulding, extrusion and/or blowing.

It is preferred when the tubular distal part of the catheter is transversely corrugated as this adds to the security against kinking. A suitable flexible and

transversely corrugated tube is known per se for preventing blocking by bending of the tube leading to urine collection bags.

In accordance with a preferred embodiment of the catheter set of the invention the package includes an elongated narrow part designed for accommodating the
5 catheter at least during wetting of the catheter and for the exit of the catheter during use.

In this embodiment the tubular part of the catheter may e.g. be in the form of a telescopically extendible tube having a maximum diameter greater than the proximal part of the catheter. Alternatively the tubular part may be in the form of an
10 extendible corrugated tubing resembling a corrugated straw which may be folded, compressed or stretched like an accordion. This embodiment can advantageously be used when the urine is led directly to an exterior container e.g. a toilet bowl.

In accordance with another preferred embodiment the package also includes a
15 broader container part for collecting the urine.

In accordance with yet another preferred embodiment of the invention the package is provided with one or more sealing devices on the exterior side of the package designed for holding and sealing the elongated end of the package after use. When using the package for collecting urine, it is possible to tie a knot
20 on the elongated part after pushing the catheter into the package but this still leaves a small amount of urine in the outer part of the package which may be spilled onto the clothes which will be embarrassing for the user.

The sealing device is preferably in the form of an adhesive sheet adhered to the package. The sheet may typically comprise a sheet of a relatively soft and pliable
25 material having an adhesive on the surface facing the outer side of the package and wherein a part of this surface is covered with a release liner which is adhered to the outer surface of the package. Thus, the sheet functions as a part of the surface of the package when not in use, and when used, the sheet is released from the release liner, which is then removed, and the top of the bag is

preferably placed at the adhesive area and the sheet is placed at the adhesive area holding and sealing the end of the bag.

The sealing device of this embodiment securely closes and seals the opening of the package and furthermore, it enables a sealing by bending the top of the
5 package and securing and sealing the same below a flap of an adhesive sheet adhered to the package the sealing device without having to push the catheter into the package which facilitates the sealing and provides a better security against spilling of urine.

The sheet may be of any suitable material e.g. the ones mentioned above. The
10 adhesive may be any suitable adhesive being compatible with the package material and the sheet material. It is preferred when the adhesive exhibit some moisture absorbing capability in order to ensure a secure sealing even if some drops of urine are spilled when sealing the top of the package after use. An moisture absorbing adhesive may be any such adhesive known per se for wound
15 or ostomy purposes, e.g. containing hydrocolloids.

A release liner may for instance be siliconized paper.

The package may be made from a water impervious layer or film of any suitable material known per se for use in the preparation of urine collection bags.

The length of the tubular part may vary according to the specific application. Of
20 course, it should not be so long that it cannot be comprised in the bag. Even at small lengths of the tubular part an effect is obtained. In a preferred embodiment the tubular part has a length at least corresponding to the narrow upper part of the package.

DETAILED DESCRIPTION OF DRAWINGS

25 Reference is made to Fig. 1. The embodiment of the catheter set of the invention shown in Fig.1 comprises a catheter 1, a package 2 for collection of urine, a sealing part 3 and a flexible tubular part 4 connected to the catheter 1. The top of the package is easily torn off at 5 being a weak point for breaking the package. Furthermore, the package comprises another weak point 6 designed for opening

the package at the distal end, if desired, during use, if the package is to function as guide to e.g. a toilet bowl or after use if it is desired to empty the bag immediately. The package is shown with an ear 7 for an easy handling of the package during and after use. Furthermore, a container 8 is shown comprising a wetting
5 fluid.

In Fig. 2 the embodiment of Fig. 1 is shown after opening the container and wetting the catheter and tearing off the top of the package and pushing the catheter until the stop engages with the bag ready for insertion. The insertion may, if desired, be performed concomitantly with the pushing out of the catheter.

- 10 Especially in the case where the catheter is of the hydrophilic coated type the catheter can be wetted to activate the hydrophilic coating prior to tearing off the top of the package at the weak point 5 and inserting the catheter into urethra. While accommodated in the elongated part of the package the catheter is thus surrounded by the wetting fluid of the container 8 after breaking off the tip of that
15 container and holding the package so that the elongated part of the package points essentially downwards to ease the transportation of wetting fluid by gravity down into the elongated part of the package.

When the catheter is in use the urine flows in through the openings in the upper part - the proximal end - of the catheter 1 and enters the inside of the package 2
20 where it passes through the upper part which, in this embodiment, is in the form of a narrow portion as compared to the lower part of the package which is formed as a broader collection part. When the urine is passing the upper part of the package 2 it also passes the flexible tubular part 4 which is present inside this part of the package and secured to the catheter 1. The flexible tube 4
25 provides the package with a certain stiffness which prevents blocking of this part by kinking or squeezing of the relatively soft and pliable package 2. In the figure the flexible tube is shown as a smooth tube but it might as well have a corrugated surface. The most important features for the tube is that it has to be both bendable and in possession of a certain stiffness.

When the user has finished the use of the catheter he can either throw the used catheter and the filled or urine contaminated package away immediately or he can close the package and transport it to the nearest convenient waste container if there are not any present at the facility.

- 5 The user might experience a problem trying to close the package of the catheter set according to the invention as it is difficult to force the catheter down into the lower part of the package especially when the user has reduced motility of the hands, and when the catheter is still present in the narrow part of the package it is almost impossible for the user to tie a liquid-tight knot on the narrow part as
10 recommended in the instructions for use of Convene EasiCath Set from Coloplast A/S.

- Reference is made to fig. 3 showing an embodiment of the package of the invention having a sealing device at the exterior side of the package. In order to solve the above problem and render it easier for the user to transport a filled
15 package it is preferred to use a different kind of closing system as e.g. a system where the upper end of the catheter set package is closed with a piece of gummed tape or tied together by extra added parts.

- A very effective sealing device comprises three pieces of film or paper and is illustrated in figures 3 - 5. Figure 4 shows how the three pieces are arranged in
20 connection with each other: an upper piece 11, a middle piece 12 and a lower piece 13. The upper piece is non-adhesive on the outer surface and adhesive on the surface facing the package, one end of this piece is adhered to the package and the other end is adhered to the middle piece 12. The middle piece 12 is non-adhesive on both surfaces and both surfaces are made of a material which
25 makes it possible to release it from adhesive surfaces without spoiling the adhesiveness. The middle piece 12 is preferably considerably larger than the one end of the upper piece 11 it is covering as this makes it easier to grab and remove the middle piece 12 from the package. The middle piece may e.g. be made from siliconised paper. The surface of the middle piece facing 12 away
30 from the upper piece 11 is facing the lower piece 13. The lower piece 13 is

adhesive on both surfaces, one surface secure the lower piece 13 to the package and the other surface secure the lower piece 13 to the middle piece 12.

- Before the closing device is used for securing and sealing the proximal end of the catheter set, the three pieces are placed on the front or the backside of the package, they are all three releasably glued together as each of them get contact with at least one adhesive surface. When the user need to close the package he pulls the middle piece 12 and the upper end of the upper piece 11 backwards, by this action the middle piece 12 is released from the lower piece 13 (only the movement of the upper piece 11 is indicated in the figure). After the user has remove the middle piece 12 from the upper piece 11, the user places the open end of the catheter set on the lower piece, this will secure the position of the open end, and then the user covers the open end of the package with the upper piece. The open end of the package is now secured between the upper and the lower piece.
- Figure 5 shows a sectional view of a package with the sealing device in a closed position.

CLAIMS

1. A catheter set comprising a catheter and a package for storing of the catheter before use and for collecting or discharging urine wherein an elongated part of the package forms a tube for accommodation of the catheter, the catheter
5 comprises a proximal part to be inserted into the urethra and a sealing part for providing a seal between the catheter and the elongated part of the package during use, CHARACTERISED IN that the catheter further comprises a distal part in the form of a tubular section having an inner diameter at least as large as the inner diameter of the proximal part of the catheter wherein the sealing part
10 is separating the proximal part of the catheter and the tubular distal part, and wherein the length of the tubular distal part is at least long enough to occupy the elongated part of the package.
2. A catheter set according to claim 1, CHARACTERISED IN that the proximal part of the catheter has a hydrophilic coating.
- 15 3. A catheter set according to claim 1 or 2, CHARACTERISED IN that the set comprises a wetting fluid integrated into the package.
4. A catheter set according to any of claims 1 - 3, CHARACTERISED IN that the tubular distal part of the catheter has an inner diameter larger than the inner diameter of the proximal part of the catheter.
- 20 5. A catheter set according to any of claims 1 - 4, CHARACTERISED IN that the tubular part is made from an extrudable, mouldable material such as a polyolefin such as polyethylene (PE) or polypropylene (PP) or a copolymer of polyethylene such as ethylene vinyl acetate (EVA) or polyvinyl chloride (PVC) or polyvinylidene chloride.
- 25 6. A catheter set according any of claims 1 - 5, CHARACTERISED IN that the tubular distal part of the catheter is transversely corrugated.

7 . A catheter set according to any of claims 1 - 6 , CHARACTERISED IN that the package has an elongated narrow part at the end where the catheter exits the package during use and preferably also a broader container part.

8 . A catheter set according to any of claims 1 - 7 , CHARACTERISED IN that
5 the package is provided with one or more sealing devices on the exterior side of the package.

9 . A catheter set according to claim 8 , CHARACTERISED IN that the sealing device comprises an adhesive sheet adhered to the package.

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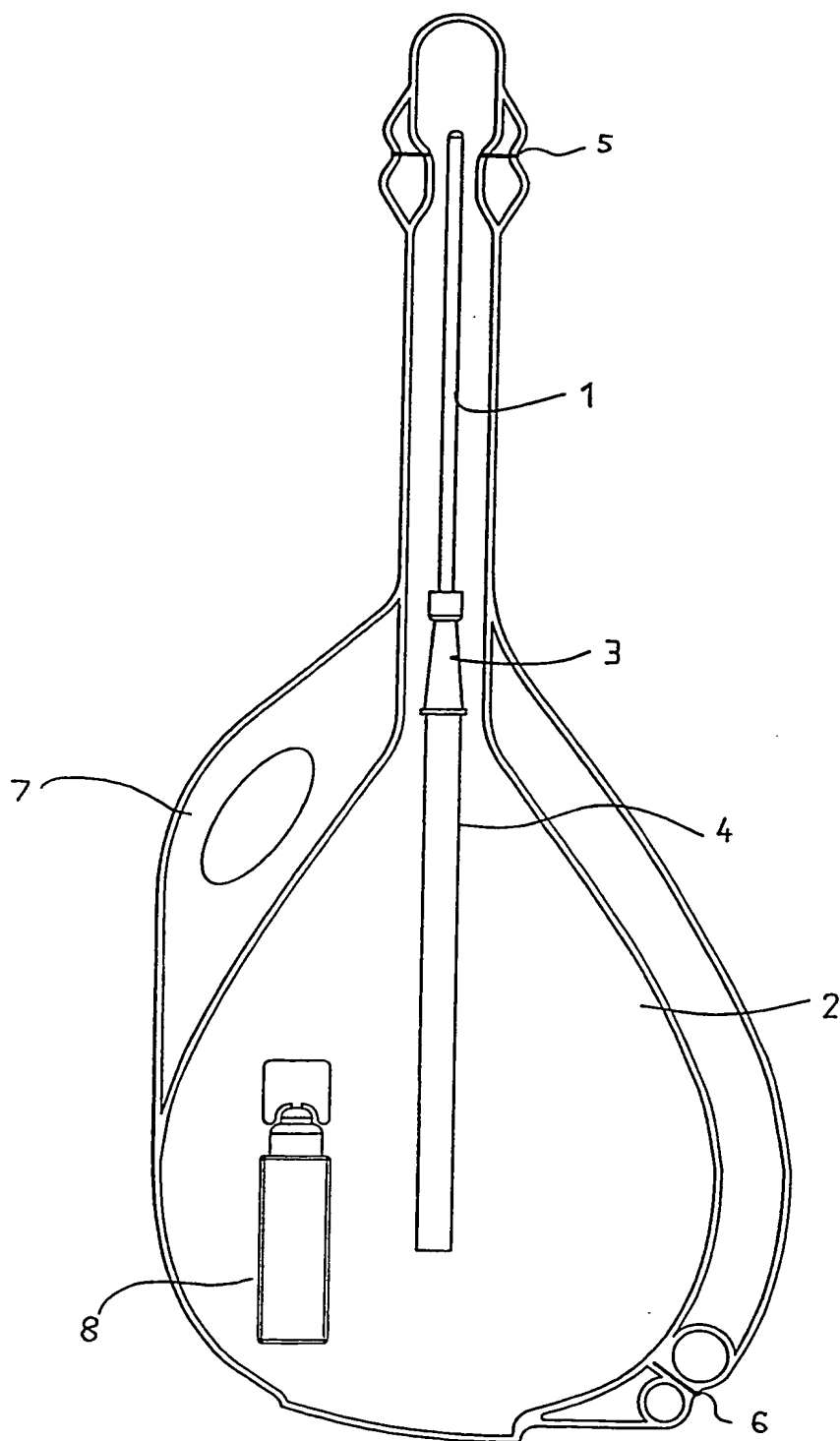


Fig. 1

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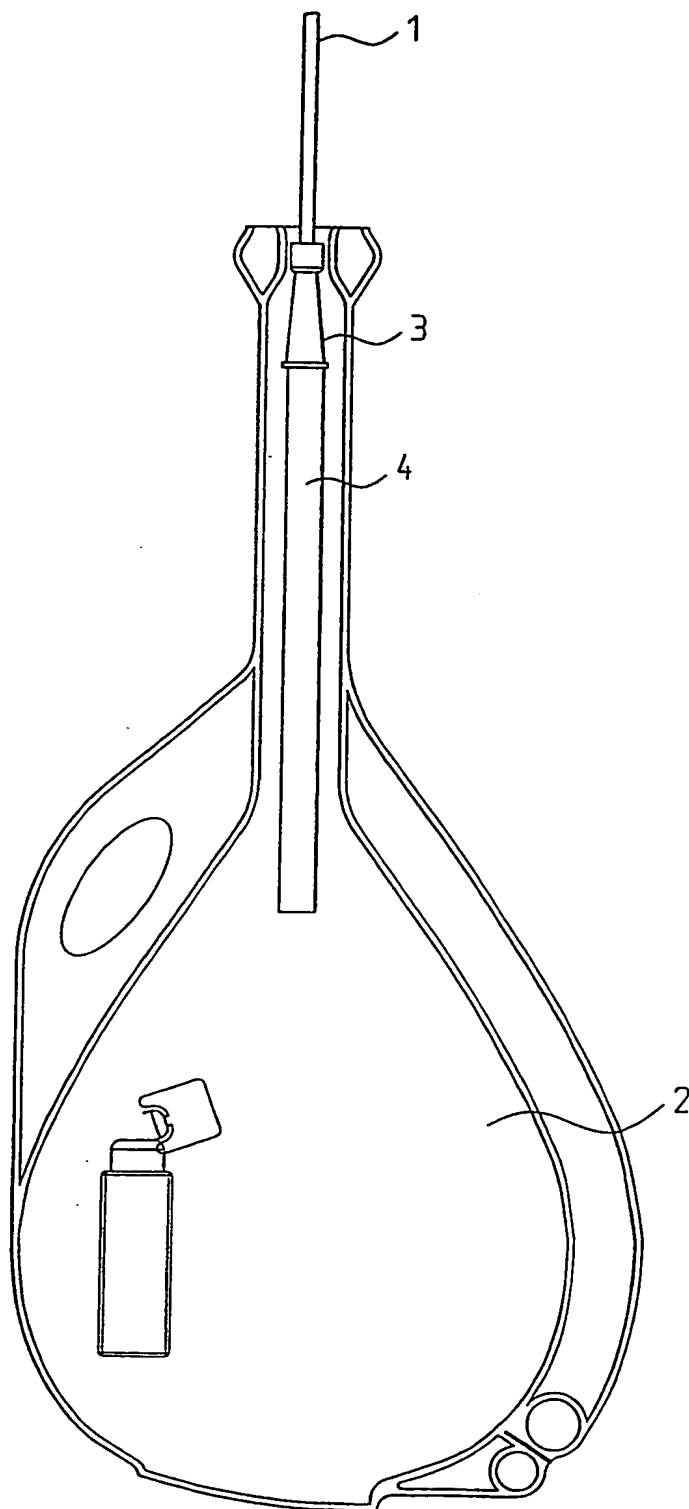


Fig. 2

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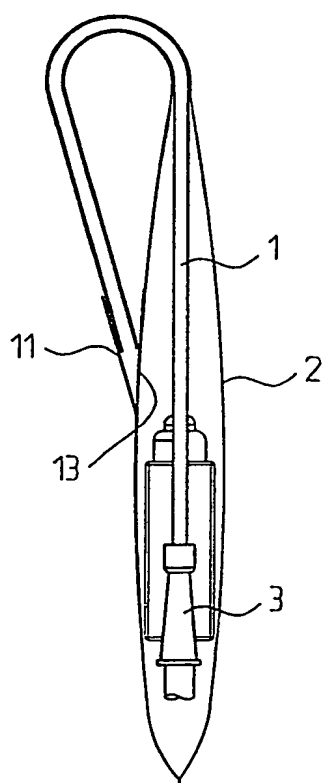


Fig. 5

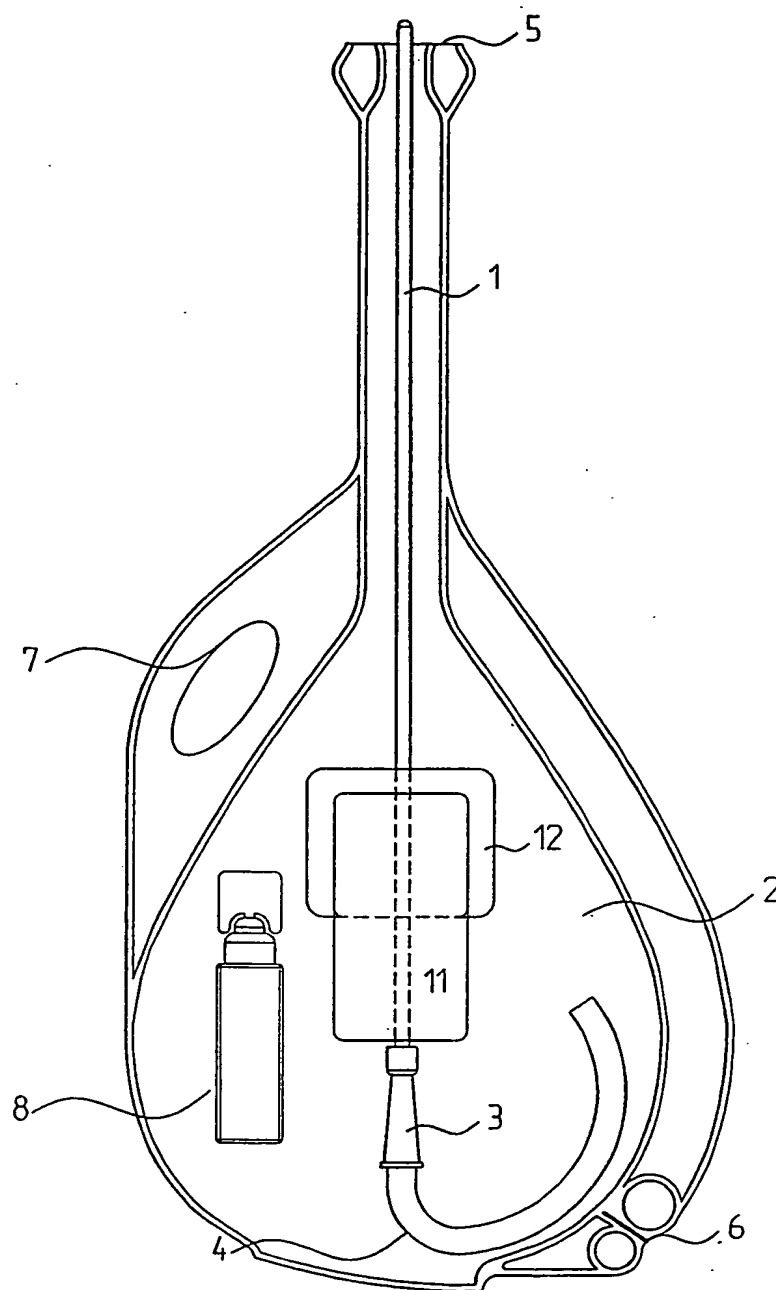


Fig. 3

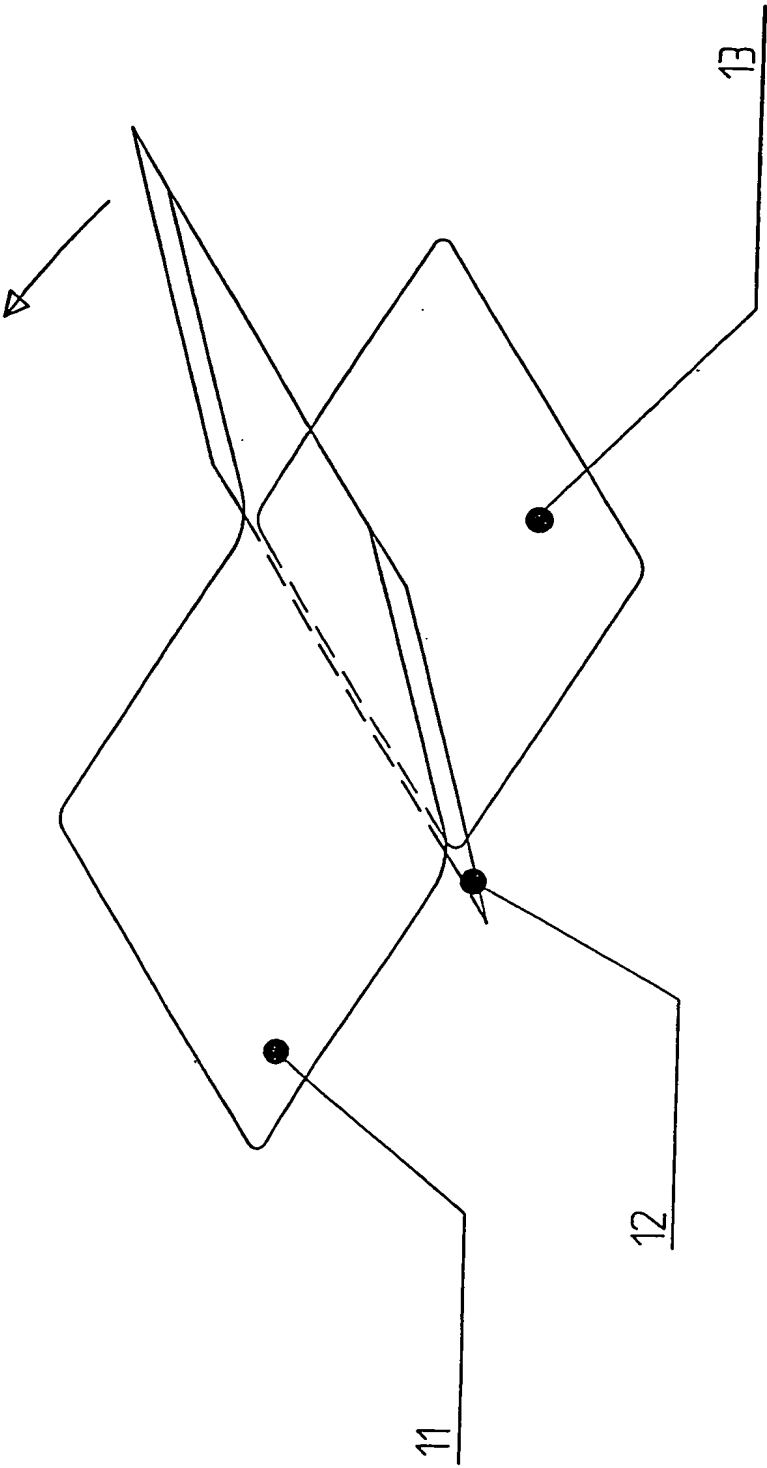


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 99/00501

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9726937 A1 (ASTRA AKTIEBOLAG), 31 July 1997 (31.07.97), page 10, line 1 - line 29; page 11, line 19 - page 12, line 9, figure 1 --	1-5,7
X	WO 9811932 A1 (COLOPLAST A/S), 26 March 1998 (26.03.98), page 14, line 18 - page 15, line 34; page 7, line 13 - line 19, figure 14 --	1-5,7
X	GB 2284764 A (MMG (EUROPE) LTD), 21 June 1995 (21.06.95), page 2, line 47 - page 3, line 15; page 3, line 35 - line 46, figures 1,2, claims 1,2, 8,9, abstract --	1,3-5



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
1 February 2000	18 -02- 2000
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International application No.

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